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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/672,049 | 09/29/2000 | Johannes Platzek | SCH-1722 | 2997 |

23599 7590 06/16/2004

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EXAMINER

WELLS, LAUREN Q

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 09/672,049 | Applicant(s) PLATZEK ET AL. | |
| | Examiner Lauren Q Wells | Art Unit 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
 4a) Of the above claim(s) 6-15, 17-22, 26-38 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 16, 21-25 and 29-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-41 are pending. Claims 6-15, 17-99, 26-38 and 41 are withdrawn from consideration, as they are directed to non-elected subject matter.

Response to Applicant's Arguments/Amendment

The Applicant's arguments filed 4/20/04 to the rejection of claims 1-5, 16, 23-25 and 39-40 made by the Examiner under 35 USC 103 have been fully considered and deemed not persuasive.

103 Rejection Maintained

The rejection of claims 1-5, 16, 23-25 and 39-40 under 35 U.S.C. 103(a) as being unpatentable over Platzek et al. (WO 97/26017) in view of Milius et al. (Jew J. Chem 1992) or in view of Riess et al. (EP 548096) is MAINTAINED for the reasons set forth in the Office Action mailed 11/19/03, and those found below.

Applicant argues, "There is no motivation to combine the cited references to arrive at a galenical formulation comprising paramagnetic perfluoroalkyl and diamagnetic perfluoroalkyl compounds. Thus, the combination of references, as cited by the Examiner, cannot render the present invention unpatentable because there is no teaching, motivation or suggestion of combining paramagnetic and diamagnetic agent. In arriving at these rejections, the Examiner fails to use the prior art as a whole, and impermissibly uses hindsight and Applicants invention as the suggestion for combining the references". This argument is not persuasive. First, it is respectfully pointed out that in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight

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reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Second, for the reasons stated in the rejections, there is motivation to combined the references.

Applicant argues, "The mere fact that it is possible to find isolated disclosures, which might be combined in such a way to produce a new invention, does not necessarily render such new invention obvious unless the prior art also contains something to suggest the desirability of the combination". This argument is not persuasive. Platzek et al. are directed to perfluoroalkyl-substituted, paramagnetic metal complexes for use in NMR, X-ray diagnostics, radiodiagnostics, and radiotherapeutic agents. Milius teach perfluoroalkylated anionic sugar phosphodiester (the instant invention labels these compounds as diamagnetic perfluoroalkyl containing substances) for utilization in numerous biomedical applications, such as contrast agents. Using these compounds in such applications provides the benefits of improving particle size, viscosity, long term storage stability, intravascular persistence, aggregability, rate of and response to phagocytosis and biodistribution. There benefits suggest the desirability of such a combination. Riess et al. teach the diamagnetic perfluoroalkyl containing substances of the instant invention for use in NMR, radiography, or sonography, and it is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that it is to be used for the very same purpose.

Applicant argues, "on page 28, first paragraph, the specification states that unexpected advantages are provided by the invention. The prior art references in no way suggest these".

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This argument is not persuasive, as page 28 of the specification does not comply with the guidelines for establishing unexpected results, as described in the MPEP. The Examiner respectfully directs Applicant to these guidelines. It is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also 716.02 (a) - (g).

Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

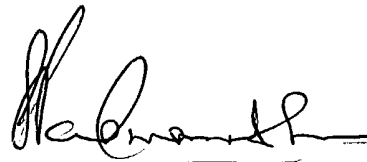
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is 571-272-0634. The examiner can normally be reached on M&R (5:30-4).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

lqw



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER